

CLAIMS

What is claimed is:

5 1. A nozzle for aerosolizing a flowable liquid formulation for delivery to a patient, comprising:

 a sheet of flexible membrane material having an entrance side to which said formulation is applied under a pressure, an exit side from which aerosol is released, and a nozzle area, which nozzle area has a plurality of pores therein through which said formulation is extruded, each of
10 said pores having an entrance aperture and an exit aperture having a pore entrance aperture size and a pore exit aperture size, wherein the ratio of pore entrance aperture size to pore exit aperture size is at least about 10:1.

 2. The aerosolization nozzle of claim 1, wherein the ratio of pore entrance aperture
15 size to pore exit aperture size is at least about 15:1.

 3. The aerosolization nozzle of claim 1, wherein the ratio of pore entrance aperture size to pore exit aperture size is at least about 25:1.

20 4. The aerosolization nozzle of claim 1, wherein each of the pores comprises two or more pore steps, each pore step having a pore step entrance aperture size and a pore step exit aperture size, wherein the entrance aperture size of each successive pore step from the entrance side to the exit side of the membrane is about 20 to about 90% of the exit aperture size of the preceding, entrance-proximal, pore step.

25 5. The aerosolization nozzle of claim 1, wherein the pores are tapered in configuration, gradually narrowing from the entrance aperture to the exit aperture.

 6. The aerosolization nozzle of claim 1, wherein said pores are positioned at a

distance of about 30 to about 70 μm apart from one another, wherein said pores in said nozzle area are at a density of least about 100 pores per square millimeter, and further wherein the membrane material has a thickness in the range of about 10 to 100 micrometers.

5 7. The aerosolization nozzle of claim 1, wherein said pores have an exit aperture diameter in the range of about 0.5 μm to about 50 μm , wherein said pores in said nozzle area are at a density of least about 200 pores per square millimeter, and further wherein the membrane material has a thickness in the range of about 20 to 30 microns.

10 8. The nozzle of claim 1, further comprising:
a removable cover sheet detachably connected to the nozzle area.

15 9. The nozzle of claim 1, wherein the exit apertures are regularly spaced in the nozzle area in rows, and further wherein the flexible membrane material is a polymer selected from the group consisting of polyimides, polyether imides, polyethers, polyesters, polyethylene and polycarbonates.

20 10. The nozzle of claim 1, wherein said membrane comprises a plurality of nozzle areas.

25 11. A container for aerosolizing a flowable liquid formulation for delivery to a patient, comprising:

(a) a sheet of flexible membrane material having an entrance side to which said formulation is applied under a pressure, an exit side from which aerosol is released, and a nozzle area, which nozzle area has a plurality of pores therein through which said formulation is extruded, each of said pores having an exit aperture and an entrance aperture having a pore entrance aperture size and a pore exit aperture size, wherein the ratio of pore entrance aperture size to pore exit aperture size is at least about 10:1;

(b) container walls connected to the sheet wherein a wall is collapsible by the application

of a force; and

(c) a liquid formulation held within the container walls.

12. The container of claim 11, characterized such that a force of about 500 pounds per square inch (psi) or less collapses the container and forces the formulation out of pores of the membrane and aerosolizes the formulation in 2 seconds or less.

13. The container of claim 12, characterized such that a force of less than 400 psi is required.

14. The container of claim 13, characterized such that a force of 200 psi or greater is required.

15. A disposable container comprising:

(a) at least one wall which is collapsible by the application of a force and having at least one opening, wherein said opening leads to an open channel having an end;

(b) a nozzle positioned at the end of the open channel, said nozzle comprising:
a sheet of flexible membrane material having an entrance side to which said formulation is applied under a pressure, an exit side from which aerosol is released, and a nozzle area, which nozzle area has a plurality of pores therein through which said formulation is extruded, each of said pores having an exit aperture and an entrance aperture having a pore entrance aperture size and a pore exit aperture size, wherein the ratio of pore entrance aperture size to pore exit aperture size is at least about 10:1; and

(c) formulation in an amount of 100 milliliters or less in the container.

16. The disposable container of claim 15, wherein said open channel comprises a seal which is peeled open upon application of a force exerted upon the collapsible wall.

17. A disposable package comprising a plurality of the containers of claim 15.

18. An aerosol delivery device comprising:
a device for holding the container of claim 15;
a mechanism for forcing the formulation through the nozzle.

5 19. A method of producing a porous membrane, comprising the steps of:
directing laser energy onto an entrance surface of a membrane and continuing to direct
the energy until the laser has created a pore having an entrance aperture and an exit aperture
having a pore entrance aperture size and a pore exit aperture size, wherein the ratio of pore
entrance aperture size to pore exit aperture size is at least about 10:1, and repeating the directing
10 a plurality of times, creating pores positioned at a distance of about 30 to about 70 micrometers
apart, creating a porous membrane with a pore density of at least about 100 pores per square
millimeter.

15 20. The method of claim 19, wherein the repeating is carried out by repositioning the
laser energy for each directing step.

21. The method of claim 19, wherein the repeating is carried out by repositioning the
membrane for each directing step.

20 22. The method of claim 19, wherein the pore is formed by a process selected from
the group consisting of a multi-step process, a grayscale process, and a dithering process, wherein
the membrane is comprised of a polymeric organic material, and wherein the membrane has a
thickness in a range of from about 10 microns to about 100 microns.

25 23. The method of claim 19, wherein the laser source is a UV excimer laser having a
wavelength of from about 150 nm to about 360 nm.

24. The method of claim 23, wherein the excimer energy density is from about 300 to
about 800 mJ/cm².

25. The method of claim 19, wherein the membrane is comprised of a material selected from the group consisting of polycarbonates, polyimides, polyethers, polyether imides, polyethylene and polyesters.

5 26. A method of making an aerosolization container, comprising:
providing a container comprising at least one wall which is collapsible by the application of a force and having at least one opening, wherein said opening leads to an open channel having an end, said container comprising formulation in an amount of 100 milliliters or less; and
10 positioning a nozzle according to claim 1 at the end of said channel, wherein said container is characterized such that a force of less in a range of about 200 psi to about 500 psi collapses the container, forces the formulation out of the pores in the nozzle, and aerosolizes the formulation in 2 seconds or less.

15 27. A method of making an aerosol delivery device, comprising producing a membrane having a plurality of pores, wherein each of said pores has an entrance aperture size and an exit aperture size, and wherein the ratio of said entrance aperture size to said exit aperture size is at least about 10:1; and
incorporating the membrane into an aerosol delivery device.